K011290

MAY 3 0 2001

510(k) Summary

Submitted by:

XMAR Corporation
2222 Delaware Drive
Cleveland Heights, OH 44106

April 19, 2001

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

1. Contact Person:

Neil Barrett Tel: (216) 731-8723 Fax: (603) 761-9489

2. Device Name and Classification:

Trade Name:	Prognost ES Radiographic X-Ray System
Classification Name:	System, X-Ray, Tomographic
Classification Panel:	Radiology
CFR Section	21 CFR 892.1740
Device Class	Class II
Device Code	90IZF

3. Intended Use:

To be used for routine radiographic and radiographic tomography examinations of the entire human anatomy, skull, spinal column, chest, abdomen, extremities, and other body parts.

4. Substantial Equivalence:

The Prognost ES system is substantially equivalent to the Combi Elevator system.

Device	Manufacturer	510(k) Number	Clearance Date
Combi Elevator	Pausch Corporation	K973864	06/17/1998

5. Device Description:

The *Prognost ES* Radiographic Systems consist of a radiographic table containing a bucky and cassette tray, integrated tube mount with manual or automatic collimator.

6. Intended Use:

The *Prognost ES* system is intended for use in medical facilities, hospitals or clinics. The system is intended for use by trained health care professionals to produce medical diagnostic x-ray images.

7. Summary of Technological Characteristics of the Device Compared to the Predicate Device:

The *Prognost ES* has the same technological characteristics as the predicate device. *Prognost ES* contains the same basic components and operating characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Mr. Neil Barrett
Regulatory Manager
XMAR Corporation
2222 Delaware Drive
CLEVELAND HEIGHTS OH 44106-3115

Re: K011290
Prognost ES, Model 0302 0000
Dated: April 19, 2001
Received: April 27, 2001
Regulatory Class: II
21 CFR §892.1740/Procode: 90 IZF

Dear Mr. Barrett:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATION FOR USE STATEMENT

510(k) Number: K 011290

Device Name: Prognost ES

Indications for Use:

To be used for routine radiographic and radiographic tomography examinations of the entire human anatomy, skull, spinal column, chest, abdomen, extremities, and other body parts.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____

(Optional Format 1-2-96)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011290